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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/690,389	10/21/2003	Benjamin Oshlack	6750-362-999	2376				
20583 JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017	7590 01/05/2007		<table border="1"><tr><td>EXAMINER</td></tr><tr><td>CHOI, FRANK I</td></tr></table>		EXAMINER	CHOI, FRANK I		
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			<table border="1"><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1616</td><td></td></tr></table>	ART UNIT	PAPER NUMBER	1616		
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1616								
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE					
3 MONTHS		01/05/2007	PAPER					

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,389

Applicant(s)

OSHLACK ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-69 is/are pending in the application.
- 4a) Of the above claim(s) 39-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 36-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 39-69 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims were directed to compositions which exhibited the concentration vs. time curves of Figures 14-17. The new claims are not limited to the same. As such, the new claims contain subject matter which was not necessarily searched in the original claims. As such, prosecution of the new claims would constitute an undue burden on the Examiner. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 25-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific formulations prepared which resulted in the concentration vs. time curves in Figures 14-17, the specification does not reasonably provide enablement for any means of providing the said curve. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

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The invention is directed to sustained release oral dosage forms containing hydromorphone and means for providing the concentration versus time curves of Figures 14,15, 16 and 17.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses sustained release oral dosage forms of hydromorphone, however, there is no indication as what other formulation would result in the graphs set forth in the above Figures.

The amount of direction or guidance present and the presence or absence of working examples: Other the specific formulations that resulted in the graphs, the specification lists numerous possible excipients which could be used to prepare the dosage form. However, there is no indication as to what other formulations would result in the graphs.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that any means for preparing the sustained release dosage forms is claimed. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine what other formulations would result in the graphs set forth in Figures 14-17.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The rejection indicated that it was the specified formulations tested that resulted in the concentration time curves. The Applicant has not provided any evidence that any hydrophobic materials and any hydrophobic fusible carrier would result in said curve. As such, one of

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ordinary skill in the art would still be required to do undue experimentation in order to determine what other formulations would result in said curves.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

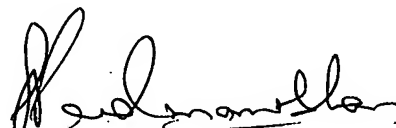
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
December 26, 2006


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER